K112591

FEB - 7 2012

PREMARKET NOTIFICATION

510(K) Summary

Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP. (Heat-seal and Self-seal)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's Identification: Address:	Safe Secure Packaging (Shenzhen) Co., Ltd Chengguang Industrial Park, No.4, Kukeng Po New Village, Guanian Town, Baoan District, 518110, Shenzhen City P.R.C.
Phone: Fax: Contact:	+86 755 27040468 +86 755 27040488 Mr. Garfield Wang
Email: Date	Wangxuebo_11@hotmail.com Dec. 01 2010
Device Name:	Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP. (Heat-seal and Self-seal).
Classification Name: Classification:	Pack, Sterilization Wrapper, Bag and Accessories Class II
Intended Use:	Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP, is intended to be used to enclose another medical device that is to be sterilized by a health provider by gravity steam and ethylene oxide (EtO). The recommended steam sterilization cycle parameters are 30 minutes at 121° C (250 °F). The recommended EtO gas sterilization cycle is 735mg/L of ethylene oxide (EtO) for 1 hour at 55°C (130 ° F) and 50% to 80%RH. The pouch's external chemical ink indicators on the pouches are intended to demonstrate that the device has been exposed to the steam or EtO

sterilization process and to distinguish between processed and unprocessed devices. The pouch is intended to allow sterilization of the enclosed medical device and also to maintain sterility (SAL=10^{-6}) of the enclosed device until used.

Predicate Device Information:

Company Name:	Winner Medical USA, Inc.
Address:	1900-H Proforma Ave. Ontario, CA 92861
510(k) number:	K062704
Device Name:	STERILIZATION POUCH WITH INDICATORS
Intended Use:	Sterilization Pouch with indicators is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121oC for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Company Name:	Winner Medical USA, Inc.
Address:	1900-H Proforma Ave. Ontario, CA 92861
510(k) number:	K051242
Device Name:	WINNER SELF SEAL STERILIZATION POUICH
Intended Use:	Winner Self Seal Sterilization Pouches are intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121oC for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

Device Description:

These pouches are manufactured from a medical grade paper and plastic film that are heat sealed on three sides. The fourth side has an adhesive tape that is used to seal the pouch or heat-sealed by the heat-seal machine. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Sterilization Pouch with Indicators has the same intended use, Essential Component, Raw material, Sterilization method, manufacturing methods and same technological characteristics as these predicate devices. Substantial equivalent to the predicate device was established by physical testing of the medical grade paper (pressure drop vs. flow and filtration efficiency) and film (thickness, tensile strength and elongation) from non-sterile, steam sterilized and ethylene oxide sterilized finished devices, as well as, performance of these finished devices (seal strength, package burst, dye migration, temperature distribution for steam and ethylene oxide sterilization, steam and ethylene oxide sterilization of biological indicators). The process indicators meet the performance requirements of ANSI/AAMI/ISO 11140-1:2005 standard entitled "Sterilization of health care products-Chemical indicators- Part 1: General requirements".

The pouches are manufactured from medical grade paper that is thermally sealed to laminated film on the left, right, and bottom of pouch. The fourth side has an adhesive tape that is used to that is used to seal the pouch or heat-sealed by the heat-seal machine prior to sterilization of the enclosed medical device. The pouches contain external chemical indicators used to indicate the pouches were processed via steam or EtO sterilization. See **Chatper 10** for a detailed device description including shelf life, sterility achievement and compatibility with steam and EtO sterilization processes and Bill of Materials.

Model numbers of the pouches:

Ref Number	Model Number	Description	Dimensions	Packaging
ABHSP100001	ABHSP	Heat-Seal Sterilization Pouch	Length: 2"~20" Width: 3"~30"	400pcs/cs—6000pcs/cs
ABHSP100002	ABHSP	Sterilization Tubing Pouch	Width: 2"—30"	/
ABSSP100001	ABSSP	Self-Seal Sterilization Pouch	Length: 2"~20" Width: 3"~30"	400pcs/cs—6000pcs/cs

Device Comparison:

Side by side testing was conducted on the Safe Secure Sterilization Pouch with Indicators and the WINNER STERILIZATION POUCH WITH INDICATORS, WINNER SELF SEAL STERILIZATION POUCH to determine substantial equivalence. Sterilant Penetration, Drying Time, Aeration, Biocompatibility, Package Integrity, Material Compatibility, Sterility Maintenance, and Chemical Indicator Efficacy (recognized standard ISO 11140-1:2005) were the parameters used to determine substantial equivalence and validate the safety and efficacy of the device.

Proposed Labeling:

A comparison with the predicate labeling confirms our claim of substantial equivalence with the predicate.

Conclusion:

The materials, performance, and functions of both the submitted device and the predicate devices are substantially equivalent and are safe and effective for their intended use. Both submitted device and predicate devices are produced by the manufacturer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Safe Secure Packaging Company, Limited
C/O Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

FEB - 7 2012

Re: K112591
Trade/Device Name: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: January 23, 2012
Received: January 24, 2012

Dear Ms. Wilkerson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112591

Device Name: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators Models: ABHSP, ABSSP.

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use __X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Mansi-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112591